REMARKS

Pending claims 1-20 stand rejected, claim 20 is hereby canceled, claims 1-20 are amended herein, and new independent claim 21 is added; accordingly, claims 1-19 and 21 are pending for examination on the merits. Entry and favorable consideration of the amendments and remarks presented herein is earnestly solicited.

In the Office Action mailed 5 April 2002, all pending claims (1-20) were rejected. Specifically, (A) claims 1-20 stand rejected under 35 U.S.C. §112, second paragraph; (B) claims 1, 2, 12 and 13 stand rejected under 35 U.S.C. §102(b) or alternatively as obvious under 35 U.S.C. §103(a) over U.S. Patent No. 5,720,770 to Nappholz et al. (Nappholz); (C) claims 1-9 and 12-15 stand rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,083,248 to Thompson et al. (Thompson); (D) claims 10 and 19 stand rejected under 35 U.S.C. §103(a) over Thompson (or Nappholz) in further view of U.S. Patent No. 5,186,170 to Varrichio et al. (Varrichio); (E) claims 11 and 20 stand rejected under 35 U.S.C. §103(a) over Thompson (or Nappholz) in further view of U.S. Patent No. 5,899,931 to Deschamp et al. (Deschamp); and (F) claims 16-18 stand rejected under 35 U.S.C. §102(b) or alternatively as obvious under 35 U.S.C. §103(a) over Nappholz. Each ground of rejection is discussed below.

(A) Claim Rejections Under 35 U.S.C. §112, second paragraph

Claims 1-20 stand rejected under U.S.C. §112, second paragraph and the Examiner has offered many helpful suggestions regarding solution of such rejection. The Applicants herewith incorporate the Examiner's suggestions and respectfully assert that such ground of rejection has been successfully addressed via this Amendment. Claim 20 has been canceled as a matter of convenience only.

Accordingly, with respect to claims 1-19 this ground of rejection has been rendered moot and should be withdrawn.

(B) Claim Rejections Under 35 U.S.C. §102(b) (and §103(a))

Claims 1, 2, 12 and 13 stand rejected over U.S. Patent No. 5,720,770 to Nappholtz et al. (Nappholz) on alternative grounds (i.e., §102(b) or §103(a)).

With respect to the §102(b) rejection, the Applicants respectfully assert that the amended claims are patentably distinct from Nappholz in that Nappholz fails to disclose aggregating data, among other distinguishing features. Since the amended claims contain at least one feature not disclosed by Nappholz, this ground of rejection stands traversed.

With respect to the §103(a) rejection, the Applicants assert that the Examiner has failed to assert a *prima facie* obviousness rejection and that the obviousness rejection based solely on Nappholz is defective. Furthermore, the Examiner relies upon solely upon Nappolz and has improperly utilizes principles of inherency in support of the rejection as to a significant limitation of the claimed invention.

The Applicants amend claims 1, 2, 12 and 13 herein and respectfully submit that said claims are clearly distinguished over Nappholz in several respects.

Amended independent claim 1 requires that *physiologic data acquired from more than one implantable medical device (i.e., at least two)* is transmitted to a centralized computing resource and analyzed. A set of instructions is formulated based at least in part on the results of the analysis and the set of instructions is transmitted to at least one (of the two) for execution therein.

Nappholz neither discloses nor suggests such a technique as Nappolz essentially relates to transporting via a modified cellular phone data from a single implanted cardiac stimulating device to a remote console and/or memory unit. As recited in Nappholz at column 8, lines 26-28:

> [I]n this manner, a continuous record is generated of the operation of ***each*** device 12, as well as the condition of each patient associated with ***the*** device 12. (***emphasis added***)

Since claims 2, 12 and 13 depend from independent claim 1 they too are distinguished over Nappholz. In addition, claims 2, 12 and 13 now recite additional elements neither disclosed nor suggested by Nappholz. Claims 2, 12 and 13 as amended include subject matter disclosed and supported in the application. Claim 13 furthermore includes claim limitations regarding the manner in which the "upgrade" is created which has no corresponding element in either Nappholz or Thompson (as set forth below).

Accordingly, the obviousness rejection of claims 1, 2, 12 and 13 - based solely on Nappholz - stands traversed and should be withdrawn.

(C) Claim Rejections Under 35 U.S.C. §103(a)

Claims 1-9 and 12-15 stand rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,083,248 to Thompson et al. (Thompson).

The Applicants suggest that the Examiner has again failed to assert a *prima facie* obviousness rejection based solely on Thompson. The Applicants hereby incorporate the discussion of amended claims 1, 2, 12 and 13 as set forth above with respect to Nappholz (above) as fully applicable to the obviousness rejection based solely on Thompson. Thompson, like Nappholz, relates to data telemetry of patient data and patient location on a single unit basis.

As noted above, claims 1-9 and 12-15 are herewith amended and claims 3-9 and 14-15 recite claim limitations neither disclosed nor suggested by Thompson. Accordingly, the Applicants respectfully request that the obviousness rejection based solely on Thompson be withdrawn.

(D) Claim Rejections Under 35 U.S.C. §103(a)

Claims 10 and 19 stand rejected under 35 U.S.C. §103(a) over Thompson (or Nappholz) in further view of U.S. Patent No. 5,186,170 to Varrichio et al. (Varrichio).

The Applicants suggest that the Examiner has again failed to assert a *prima facie* obviousness rejection based on Thompson (or Nappholz) in further view of Varrichio. The Applicants hereby incorporate the discussion as set forth above with respect to Nappholz and Thompson (above) as fully applicable to the present obviousness rejection.

In addition, Varrichio merely adds a purportedly less complicated asynchronous communication technique. However, since neither Thompson nor Nappholz teach or suggest claim limitations of independent claims 1 or 14 (upon which claims 10 and 19 depend, respectively), the combination of Thompson (or Nappholz) and Varrichio also fails to render the subject matter of claims 10 and 19 obvious.

For the above and foregoing reasons, the Applicants respectfully request that this ground of rejection be withdrawn.

(E) Claim Rejection Under 35 U.S.C. §103(a)

Claims 11 and 20 stand rejected under 35 U.S.C. §103(a) over Thompson (or Nappholz) in further view of U.S. Patent No. 5,899,931 to Deschamp et al. (Deschamp). Since claim 20 is herein canceled without prejudice or disclaimer, only claim 11 stands rejected by the recited combination of references.

The Applicants suggest that the Examiner has again failed to assert a *prima facie* obviousness rejection based on Thompson (or Nappholz) in further view of Deschamp. The Applicants hereby incorporate the discussion as set forth above with respect to Nappholz and Thompson (above) as fully applicable to the present obviousness rejection.

In addition, Deschamp merely adds a purportedly a synchronous communication technique. However, since neither Thompson nor Nappholz teach or suggest claim limitations of independent claim 1 (upon which claim 11 depends), the combination of Thompson (or Nappholz) and Deschamp also fails to render the subject matter of claim 11 obvious.

For the above and foregoing reasons, the Applicants respectfully request that this ground of rejection be withdrawn.

(F) Claim Rejections Under 35 U.S.C. §102(b) (and §103(a))

Claims 16-18 stand rejected under 35 U.S.C. §102(b) or alternatively as obvious under 35 U.S.C. §103(a) over Nappholz.

However in the text describing this ground of rejection the Examiner refers to "*Thompson*" (which the Applicants infer was a typographical error and that the Examiner in fact meant to refer only to "Nappholz").

The Applicants suggest that the Examiner has again failed to assert a *prima facie* obviousness rejection based solely on Nappholz. The Applicants hereby incorporate the discussion as set forth above with respect to Nappholz (above) as fully applicable to the present obviousness rejection. The Applicants trust that, particularly in view of the amended claims, the Examiner might now better appreciate the applicability of using computer processing power such as provided by a so-called super computer, multi-processor workstation and networked cluster of computers.

For the above and foregoing reasons, the Applicants respectfully request that this ground of rejection be withdrawn.

II. Conclusion

For the foregoing reasons, the grounds of rejection stand traversed and should be withdrawn and claims 1-19 (as amended) and new claim 21 should be allowed to proceed to timely issuance as Letters Patent.

A summary of the amendments herein are provided in the accompanying sheets entitled, **MARKED-UP VERSION OF PENDING CLAIMS**.

Respectfully submitted,

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MARKED-UP VERSION OF PENDING CLAIMS

What is claimed is:

1. (AMENDED) A computerized method of controlling one or more [IMDs] implantable medical devices deployed in one or more patients, said [IMDs] implantable medical devices having firmware or software, comprising the steps of:

transmitting via a network communication link a set of historical physiologic data previously gathered from at least [one of the IMDs] two implantable medical devices to a centralized computing resource external to a[ny] patient;

analyzing the set of historical physiologic data so transmitted according to a suitable physiologic model and generating a set of results of the analysis of the set of historical physiological data;

determining a set of instructions comprising an [IMD] implantable medical device therapy [treatment] regimen based at least in part on the set of results of the analysis of the set of historical physiologic data; and

transmitting via [a] the network communication link or a separate network communication link the set of instructions to at least one of the [appropriate IMD] at least two implantable medical devices for execution by the [IMD] at least one or more implantable medical devices in accordance with [its] a firmware- or a software-implemented executable routine.

2. (AMENDED) [The] A method [of] according to claim 1, wherein the network communication link or the separate network communication link comprises a radio frequency link, a hard-wired link, an infrared-band link, or other type of a wireless communication link.

3. (AMENDED) [The] A method [of] according to claim 2, wherein the network communication link or the separate network communication link comprises a hybrid link.

4. (AMENDED) [The] A method [of] according to claim 3 wherein the hybrid link comprises a radio frequency link from [an IMD] said at least two implantable medical devices to a routing instrument, and a secondary network link from the routing device to the central computing resource.

5. (AMENDED) [The] A method [of] according to claim 4 wherein the secondary network link is a direct dial up connection.

6. (AMENDED) [The] A method [of] according to claim 4 wherein the secondary network link is an area network.

7. (AMENDED) [The] A method [of] according to claim 6 wherein the area network is a [LAN] large area network.

8. (AMENDED) [The] A method [of] according to claim 6 wherein the area network [is] comprises a [WAN] wide area network.

9. (AMENDED) [The] A method [of] according to claim 6 wherein the area network [is] comprises at least a one of an internet-, an intranet-, an extranet- or a world wide web-based network.

10. (AMENDED) [The] A method [of] according to claim 4, wherein the secondary network communication link comprises an asynchronous link.

11. (AMENDED) [The] A method [of] according to claim 4, wherein the secondary network communications link comprises a synchronous link.

12. (AMENDED) [The] A method according to [system of] claim 1, wherein each of the [one] two or more [IMDs] implantable medical devices comprises one or more of: a pacemaker, a [PCD] pacemaker/cardioverter/defibrillator, a defibrillator, an oxygen sensing device, a nerve stimulator, a muscle stimulator, a drug pump, a neurological stimulator, a physiological signal recorder or an implantable monitoring device.

13. (AMENDED) A [The computerized] method [of] according to claim 1, comprising the further step of:

transmitting from [a] said centralized computing resource to one or more [IMDs] of said implantable medical devices an upgrade to the [IMD] implantable medical device firmware or software, wherein said upgrade comprises the following steps:

aggregating the set of historical physiological data with an additional set of data;

performing a complex nonlinear analysis upon the aggregated sets of data to generate a predictive signal output; and

incorporating said predictive signal output into the set of instructions.

14. (AMENDED) A computerized information network system linking [one or more IMDs] at least two implantable medical devices deployed in one or more patients to a centralized external computer via a data communication network, said computerized information network comprising:

a central computing resource accessible by the data communication network, said central computing resource capable of applying a physiologic model to an aggregate set of patient data recorded by [an IMD] at least two implantable medical devices;

at least one routing instrument capable of wireless communication with at least one [IMD] of said at least two implantable medical devices deployed in a patient, said at least one routing instrument being capable of performing a data communication sequence with the data communication network.

15. (AMENDED) [The] A computerized information network [of] according to claim [13] 14, wherein the data communication network comprises a direct link between the at least one routing instrument and the central computing resource.

16. (AMENDED) [The] A computerized information network [of] according to claim [13] 14, wherein the central computing resource comprises a supercomputer and the physiologic model comprises a complex nonlinear analysis algorithm.

17. (AMENDED) [The] A computerized information network [of] according to claim [13] 14, wherein the central computing resource comprises a multi-processor workstation.

18. (AMENDED) [The] A computerized information network [of] according to claim [13] 14, wherein the central computing resource comprises a networked cluster of computers.

19. (AMENDED) [The system of] A computerized information network according to claim [13] 14, wherein the data communication protocol comprises an [is] asynchronous protocol.

21. (NEW) A computerized method of reprogramming and/or updating operational parameters of an implantable medical device by performing mass data acquisition, data aggregation, common data analysis and providing a new instruction set to one or more implantable medical devices via a computerized network, comprising the steps of:

acquiring a historical physiologic data set stored in a data storage medium of an implantable medical device deployed in a first patient;

aggregating the data set with a plurality of other historical physiologic data sets to generate an aggregated data set;

performing a complex analysis of the aggregated data set to produce an output data set, wherein said output data set includes at least a one of the following:

a predictive output, an emerging trend output, a revised therapy output, a revised pacing engine output, a mass-diagnosis output, a centralized therapy output, a diagnostic output, a disease state output, a physiologic-validation output, an upgrade output, or a reprogramming output; and

communicating said output data set as an operational parameter to at least one implantable medical device.